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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,240	12/26/2000	H. Kirk Hammond	220002056723	6646

25226 7590 06/06/2002

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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	8

DATE MAILED: 06/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/750,240	HAMMOND ET AL.	
	Examiner	Art Unit	
	Michael Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sh et with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-100* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1632.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 10, 11, 19, 20, 25, 26, 29-32, drawn to methods of enhancing cardiac function by administering a vector encoding β_1-AR, classified in class 514, subclass 44.

II. Claims 1-7, 10, 19, 20, 25, 26, 29-32, drawn to methods of enhancing cardiac function by administering a vector encoding β_2-AR, classified in class 514, subclass 44.

III. Claims 1-7, 12, 19, 20, 25, 26, 29-32, drawn to methods of enhancing cardiac function by administering a vector encoding GRK inhibitor, classified in class 514, subclass 44.

IV. Claims 1-7, 13-23, 25-33, 35, drawn to methods of enhancing cardiac function by administering a vector encoding AC_{VI}, classified in class 514, subclass 44.

V. Claims 1-8, 19, 20, 25, 26, 29-32, drawn to methods of enhancing cardiac function by administering a vector encoding two β-ASP, classified in class 514, subclass 44.

VI. Claims 1-7, 9, 19, 20, 25, 26, 29-32, drawn to methods of enhancing cardiac function by administering a vector encoding β-ASP followed by administering a vector encoding a different β-ASP, classified in class 514, subclass 44.

VII. Claims 36-38, 40, 47, 48, 51, 53-58, 64, 65 and 68 drawn to viral particles encoding β_1-AR, proviral particles encoding β_1-AR, and method of making such viral particles, classified in class 435, subclass 91.4.

VIII. Claims 36-38, 41, 42, 45-51, 53-58, 59, 62-68 drawn to viral particles encoding AC_{VI}, proviral particles encoding AC_{VI}, and method of making such viral particles, classified in class 435, subclass 91.4.

IX. Claims 36-38, 41, 47-49, 51, 53-58, 64-66 and 68 drawn to viral particles encoding AC_{II}, proviral particles encoding AC_{II}, and method of making such viral particles, classified in class 435, subclass 91.4.

X. Claims 36-38, 41, 47-49, 51, 53-58, 64-66 and 68 drawn to viral particles encoding AC_V, proviral particles encoding AC_V, and method of making such viral particles, classified in class 435, subclass 91.4.

XI. Claims 43, 44, 60, 61, 70-72, 86-88 and 91-96 drawn to DNA encoding chimeric AC, vectors encoding chimeric AC, and transfected cells encoding chimeric AC, classified in 536/23.1.

XII. Claim 52, drawn to a cell transfected with a vector encoding a β-ASP, classified in class 435, subclass 325.

XIII. Claims 73-78, 89, 90 and 97-100 drawn to DNA encoding human AC_{VI}, vectors encoding human AC_{VI}, and transfected cells expressing human AC_{VI}, classified in 536/23.1.

XIV. Claims 79-81, drawn to proteins encoding chimeric AC, classified in class 530, subclass 350.

XV. Claims 82-85, drawn to proteins encoding human AC_{VI}, classified in class 435, subclass 183.

The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: vectors encoding $AC_{V, II}$ and $_{VI}$, GKR, β1-AR and β2-AR were known in the art at the time of filing. Ishikawa (US Patent 5,334,521, Aug. 2, 1994) taught isolated polynucleotides and polypeptides encoding AC_V and $_{VI}$, Koch (1995, Science, Vol 268, pages 1350-1353) taught isolated polynucleotides encoding GKR, and Hammond (1993, J. Clin. Invest., Vol. 92, pages 2644-2652) taught polynucleotides encoding β-AR.

Groups I-IV and V or VI are unrelated because they have different modes of operation and function differently. A vectors encoding two β-adrenergic signaling proteins or administering vectors encoding different β-adrenergic proteins encompasses delivering DNA encoding proteins from two different metabolic pathways causing different function and mode of operation than a vector with one β-adrenergic signaling protein. The consideration of potential

synergistic effects obtained using a vector encoding two β-adrenergic signaling proteins are not required for a vector with one β-adrenergic signaling protein.

Groups I and VII are related as process of using viral particles encoding β_1-AR and process of making the viral particles. The methods are unrelated because the steps require to make the product are materially distinct and separate than those required to enhance cardiac function using viral particles. The burden required to search the method of using with the making would be undue. The generic claims will only be examined along with the elected invention (MPEP § 806.05(i)).

Groups I-X and XI or XIV are unrelated because chimeric and non-chimeric proteins have different modes of operation and function differently. For example, β1-AR has a different function and mode of operation than chimeric AC protein because the chimeric protein may provide non-cell signaling functions. The consideration required for chimeric proteins are not required for non-chimeric proteins. The burden required to search chimeric proteins and non-chimeric proteins together would be undue. The classification of chimeric and non-chimeric proteins differ. Therefore, restriction of vectors and methods based on the difference in chimeric and non-chimeric protein is proper.

Groups IV and VIII are related as process of using viral particles encoding AC_{VI}, and process of making the viral particles. The methods are unrelated because the steps require to make the product are materially distinct and separate than those required to enhance cardiac function using viral particles. The burden required to search the method of using with the

making would be undue. The generic claims will only be examined along with the elected invention (MPEP § 806.05(i)).

Groups V and IX are related as process of using viral particles encoding AC_{II}, and process of making the viral particles. The methods are unrelated because the steps require to make the product are materially distinct and separate than those required to enhance cardiac function using viral particles. The burden required to search the method of using with the making would be undue. The generic claims will only be examined along with the elected invention (MPEP § 806.05(i)).

Groups VI and X are related as process of using viral particles encoding AC_{V}, and process of making the viral particles. The methods are unrelated because the steps require to make the product are materially distinct and separate than those required to enhance cardiac function using viral particles. The burden required to search the method of using with the making would be undue. The generic claims will only be examined along with the elected invention (MPEP § 806.05(i)).

Groups VII-X and XIII-XV are unrelated. The methods used to make viral particles is patentably distinct from DNA encoding human AC_{VI} protein or chimeric AC protein because the method is used to produce virus while the DNA can be used as a probe. The steps required to make the virus are not required for the DNA, and the DNA does not have to be made in a viral particle. The burden required to search the method of making viral particles with DNA encoding human AC_{VI} and a chimeric AC, and proteins thereof would be undue.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL C. WILSON
PATENT EXAMINER